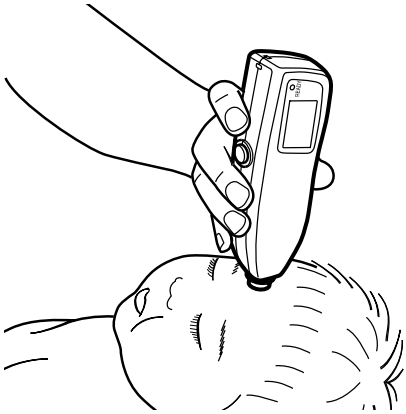
KONICA MINOLTA

Jaundice Meter JM-103

Instruction Manual



Incorrect use of the instrument may result in accidents, so follow the instruction manual to ensure correct and safe operation.

Safety Symbols

The following symbols are used in this manual and on the instrument to prevent accidents that may occur as a result of incorrect use of the instrument.

Denotes a sentence regarding a safety warning or note. Read the sentence carefully to ensure safe and correct use.

Denotes a prohibited operation.
The operation must never be performed.

Denotes an instruction.
The instruction must be strictly adhered to.

Denotes a prohibited operation.
Never disassemble the instrument.

Denotes an instruction.
Disconnect the AC power cord from the AC outlet.

This symbol indicates type BF Applied Part. The instrument provides a particular degree of protection against electric shock, particularly the leakage current and reliability of the protective earth connection with an F-TYPE APPLIED PART. F-TYPE APPLIED PART indicates applied part isolated from all other parts of the instrument to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated mains voltage is applied between the applied part and earth.

This symbol indicates alternating current (AC).

This symbol indicates direct current (DC).

Notes on this Manual

- Copying or reproduction of all or any part of the contents of this manual without KONICA MINOLTA SENSING's permission is strictly prohibited.
- The contents of this manual are subject to change without prior notice.
- Every effort has been made in the preparation of this manual to ensure the accuracy of its contents. However, should you have any questions or find any errors, please contact a KONICA MINOLTA SENSING authorized service facility.
- KONICA MINOLTA SENSING will not accept any responsibility for consequences arising from the use of the instrument.

Authorized Standards

For North America

UL, cUL:

WITH RESPECT TO ELECTRICAL SHOCK,FIRE AND MECHANICAL HAZARDS ONLYIN ACCORDANCE WITH UL 60601-1AND CAN/CSA C22.2 No. 601.1

For Europe

CE (Medical Device Directive):

This instrument complies with EN60601-1, EN60601-1-2, and EN ISO13485, and EN ISO14971.

SAFETY PRECAUTIONS

To ensure correct use of this instrument, read the following points carefully and adhere to them. After reading this manual, keep it in a safe place where it can be referred to anytime a question arises.

WARNING

Failure to adhere to the following points may result in death or serious injury.

Do not use the instrument in areas where flammable or combustible gases (anesthetic gas, gasoline fumes etc.) are present. Doing so may result in a fire.

Always use the charger unit (JM-A30) and the AC adapter (JM-A31, including the power cord) that are supplied with the instrument, and connect the adapter to an AC outlet (100V, 50/60Hz). Using a charger unit and AC adapter other than those mentioned above or connecting to a voltage other than the one specified may result in damage to the instrument, charger or AC adapter, fire or electric shock.

Do not insert or disconnect the AC power cord's plug with wet hands. Doing so may cause electric shock.

Do not disassemble or modify the instrument, Charger unit or AC adapter. Doing so may cause a fire or electric shock.

Take special care not to allow liquid or metal objects to enter the instrument or charger unit. This may cause a fire or electric shock. Should liquid or metal objects enter the instrument, turn the power OFF immediately, disconnect the AC adapter from the AC outlet, and contact the nearest KONICA MINOLTA SENSING authorized service facility.

The instrument, Charger unit and AC adapter should not be operated if they are damaged, or if smoke or odd smells occur. Doing so may result in a fire. In such situations, turn the power OFF immediately, disconnect the AC adapter from the AC outlet, and contact the nearest KONICA MINOLTA SENSING authorized service facility.

CAUTION

Failure to adhere to the following points may result in injury or damage to the instrument or other property.

Never press the measuring probe when it is directed to the eyes. Doing so may cause eye damage.

Do not place the instrument on an unstable or sloping surface. Doing so may result in the instrument or Charger unit dropping or overturning, causing injury. When you carry the instrument, take care not to let it drop.

Make sure that the instrument is placed near the AC outlet and that the AC power cord's plug can be easily connected and disconnected.

CONTENTS

SAFETY PRECAUTIONS 2
Foreword 5
Contents of the package 7
Notes on Use 7
Notes on Storage 9
Disposal Method 9
Names of Parts 10
1) JM-103 main body 10
2) Charger unit JM-A30 11
3) AC adapter JM-A31 11
Reading the Display 12
Preparation 13
1) Charging 13
2) Inspecting 15
3) Attaching the Strap 18
4) Selecting the Unit of Measurement 19
Measurement 21
Setting the Number of Average Measurements 21
Measuring Procedure 23
Removing from Charger 23
Single Measurement 24
Average Measurement (example using five times as the average) 25
Storing the Instrument 28
Trouble Shootings 29
Error Messages 29
Check Points before Repairing 31
Maintenance and Inspections 32
Cleaning 32
Specifications 33
Appendix 35
EMC Guidance (electromagnetic emissions) 35
EMC Guidance (electromagnetic immunity) 36
Measuring Principle 38
Clinical Test Result Report 40

Foreword

Safety Notes

This instrument is designed for estimating total serum bilirubin concentration, that is necessary for the screening of jaundice in newborn infants. It must be used for newborn infants only.

Never press the measuring probe when it is directed to the eyes. Doing so may cause eye damage.

To prevent kernicterus in newborn infants, it is very important to detect jaundice in its early stages.

This hand-held jaundice meter allows a quick, non-invasive estimate of total serum bilirubin concentration, necessary for the control of jaundice in newborn infants.

Measurements are taken automatically by simply placing the instrument's measuring probe against the forehead or sternum of the infant and pressing it gently, and the measured value is displayed.

This facilitates use of the instrument for infants who are still kept in incubators and provides suitable screening for jaundice. This will also help detect jaundice in its early stages.

This instrument considers the yellowness of the skin, which consists of epidermis, dermis and subcutaneous tissue as the optical density difference at two wavelengths, and it calculates the difference only for the subcutaneous tissue by measuring the difference between the two optical paths.

Hemolytic jaundice

Normally, in the case of hemolytic jaundice that appears before the age of three days, measurement of total serum bilirubin concentration must also be taken. (The correlation between the measured value taken by the instrument and total serum bilirubin concentration drops substantially due to physiologic factors.)

Precocious jaundice

If there is a possibility that the newborn infant is suffering from precocious jaundice (incompatible blood type, hemolytic jaundice), it is necessary to take frequent measurements or measure the total serum bilirubin concentration as well. (There is a possibility that bilirubin concentration in the subcutaneous tissue rises slower than the total serum bilirubin concentration.)

When the newborn infant is undergoing photo-therapy

During photo-therapy, the bilirubin concentration in the subcutaneous tissue under the area exposed to light decreases before the total serum bilirubin concentration does, so it is necessary to limit the use of this instrument only when photo-therapy equipment is used from the back of the patient or affix a light-blocking patch to the measuring point on the forehead or chest. (In areas exposed to light, there are some cases in which only the bilirubin concentration in the subcutaneous tissue decreases before the total serum bilirubin concentration improves. In addition, if the total serum bilirubin concentration increases again after therapy, there is a possibility that the bilirubin concentration in the subcutaneous tissue will increase later.)

Measuring point

Measurements must be taken on the forehead or sternum, where a sufficient amount of blood is circulated. (There is a chance that the bilirubin concentration in the subcutaneous tissue is low for areas with small amounts of blood and areas in which the subcutaneous tissue is subject to keratinization.)

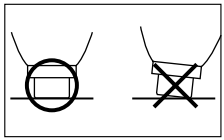
Contents of the package

Before using the instrument, check to ensure that the following items are included in the package.

1) Jaundice Merer JM-103 × 1
2) Charger Unit JM-A30 × 1
3) AC Adapter JM-A31 × 1
4) Strap × 1
5) Instruction Manual × 1

Notes on Use

- This instrument should be used under the following operating conditions.
  - Temperature of 0 to 40°C (32 to 104°F), relative humidity of 30 to 85%, with no condensation.
  - Atmospheric pressure of 700 to 1060 hPa (altitude of -400 to 3000m).
- When taking measurements, place the measuring probe perpendicular to the measuring point and then push it gently as shown below. Placing the measuring probe at an angle may result in fluctuation of measured value.



- This instrument is a precision instrument, so it should not be dropped, exposed to shocks and strong vibrations, nor should heavy objects be placed on it. Failure to observe these cautions may cause breakdown.
- Do not use the instrument in areas where it may be exposed to rain or water since it is not splash/water-proof. Also take special care not to allow blood or other liquids to come in contact with the instrument.

- Do not use the instrument on a point where there is excessive vibration. In addition, to avoid excessive impact on the instrument, it should be handled gently. Failure to observe this may cause breakdown.
- Accurate measurement data may not be obtained in the following cases.
  - When ambient light (e.g. panel light, fluorescent light, infrared heat lamp, direct sunlight) is too strong
  - When influenced electromagnetically by other electronic devices (e.g. near electrical appliances like TV, medial device)
  - When a mobile telephone is used during measurement
- This instrument has a built-in battery. Do not disassemble the instrument to replace the battery.
- Use the Charger unit (JM-A30) and AC adapter (JM-A31) that are supplied with the instrument.
- The Charger unit (JM-A30) and AC adapter (JM-A31) are solely designed for use with the JM-103, so they must never be used with any other instrument.
- This instrument emits intense light to take measurements. Measurements should only be taken of the forehead or sternum, and the instrument should never be allowed to emit light directly into the eyes.
- If the instrument gets dirty, wipe it with a dry cloth or a cloth moistened with mild, neutral detergent. (Never use a solvent such as thinner or benzene to clean the instrument, since it may dissolve its casing.)
- The measuring probe should be cleaned by wiping with medicinal alcohol before use.

Notes on Storage

- This instrument should be stored under the following storage conditions.
  - Temperature of -10 to 60°C (14 to 140°F), relative humidity of 10 to 95%, with no condensation.
  - Atmospheric pressure of 700 to 1060 hPa (altitude of -400 to 3000m).
- When storing the instrument:
  - Do not store the instrument in an area where it will be ex-posed to water.
  - Do not store the instrument in an area where direct sunlight, pressure, temperature, humidity, ventilation, sunlight, dust, strong magnetic fields, and/or saline or sulphurous atmospheres may affect the instrument.
  - Do not store the instrument on an inclined surface or on a surface which may be subject to vibrations or physical shock. (Also avoid vibrations or physical shock during transportation.)
  - Do not store the instrument in areas where chemicals are stored or where gas may be emitted.
  - The instrument and its accessories should be cleaned thoroughly and stored properly to make sure that there will be no problems when they are used again. (For the cleaning method, refer to **"Cleaning"** on page 32.)

Disposal Method

- The instrument has a built-in Ni-MH battery. Do not disassemble the instrument or remove the battery. To dispose of or replace the battery, contact the nearest KONICA MINOLTA SENSING authorized service facility.
- When disposing of the instrument or its accessories, local laws and regulations must be observed.

Names of Parts

1) JM-103 main body

POWER switch

- Slide this switch to turn the power ON/OFF.
- Using this switch in combination with the RESET button allows you to switch to check mode and change the unit of measurement.

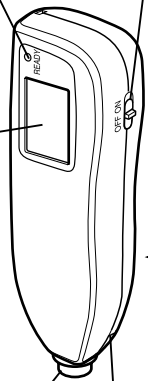
READY lamp

Lights up to indicate that the instrument is ready for the next measurement.

Display

Displays the measured value etc.

✻For the method of reading the display, refer to **"Reading the Display"** on page 12



Charger contact

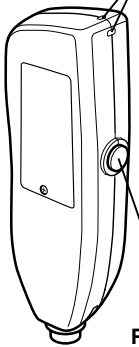
Used to connect the Charger unit.

Measuring probe

Takes measurement when pressed against the measuring point.

Strap attachment area

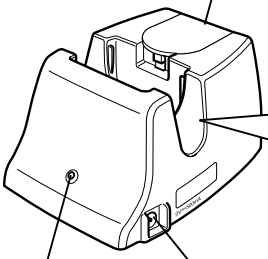
Attach the strap.



RESET button

- Deletes the currently displayed measured value and prepares for the next measurement.
- Using this switch in combination with the POWER switch allows you to switch to check mode and change the unit of measurement.
- In addition, holding this button down allows you to set the number of average measurements to be performed.

2) Charger unit JM-A30



Checker cover

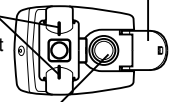
To check the instrument, open this cover.

Standard checker values

The reference values for check mode are given.

Charger jack

Used to connect the main body.



Checker

Checks whether the instrument is operating correctly by taking measurement in check mode.

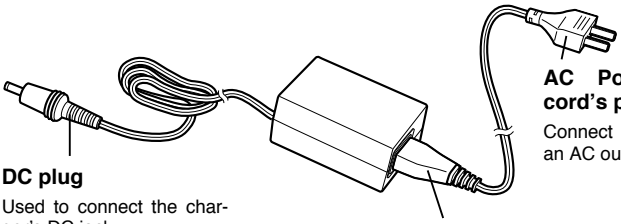
Charger lamp

Lights up to indicate that the instrument is currently charged.

DC jack

Used to connect the AC adapter.

3) AC adapter JM-A31



AC Power cord's plug

Connect into an AC outlet.

DC plug

Used to connect the charger's DC jack.

AC Power cord

Reading the Display

The following items are displayed on the instrument display.

✻In the following drawing, all the items are lit for explanatory purposes. In actual operation, there are no cases where all of them are lit at the same time.

Optical path

When performing inspections with the checker, this will be illuminated when the L value is displayed (long optical path) and extinguished when the S value is displayed (short optical path).

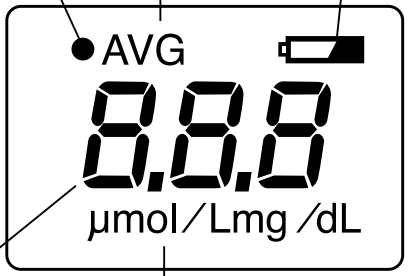
AVG

Lights up during averaging measurement.

Battery Indicate (Battery mark)

Battery mark blinks when the battery power is low.

✻For details on battery display, refer to **"Battery Indication"** on page 30.



Value

The measured values, and other information will be displayed.

Unit

Displays the unit of measurement. (mg/dL or µ mol/L)

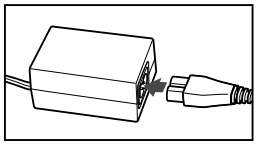
Preparation

Before starting measurements using this instrument, follow the procedure given below to ensure that measurements are stable.

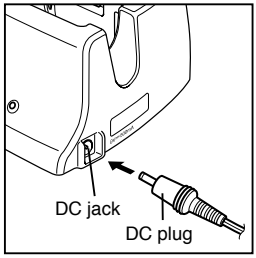
1) Charging

- Ensure that the batteries have been charged when using it for the first time.
- Ensure that JM-103 should be always placed in the charger unit to charge the battery when not using the instrument for measurement.
- The battery display will blink when the battery power is low.

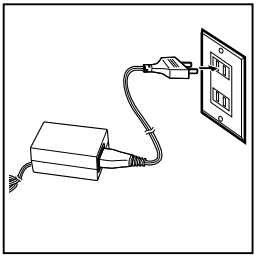
1 **The power cord and AC adapter are supplied separately. Before using the instrument, make sure that the power cord is connected to the AC adapter.**



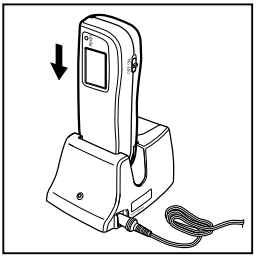
2 **Connect the AC adapter's DC plug to the DC jack of the Charger unit.**



3 Connect the AC Power cord's plug into an AC outlet.



4 Set the POWER switch on the main body to OFF, and then place the instrument on the charger unit.

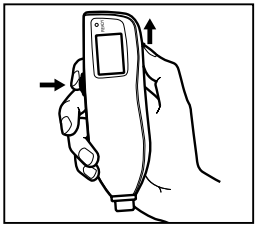


- Make sure that the display faces toward you. When the instrument is set on the Charger unit properly, the CHARGER lamp will light up.
- Charging will be completed in approximately 32 hours. Measurement can be performed approximately 400 times with fully charged battery.
- Measurement can be performed approximately 100 times with 6 hours battery charged.
- The power of the batteries will be diminished if the instrument is left uncharged for long periods of time, so ensure that it is recharged prior to use.

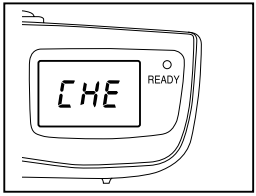
2) Inspecting

- The instrument can be easily checked to ascertain that it is performing measurement correctly, by using the checker supplied with the Charger unit.
- It is recommended that the instrument be checked once or more each day it is used.
- Since the configuration of this instrument differs from that of old models, never use conventional checkers.
- Do not touch the checker's surface with fingers. If the checker gets dirty, wipe it with a soft cloth dampened with water, then wipe it with a dry cloth.

1 Set the POWER switch to ON while holding down the RESET button.

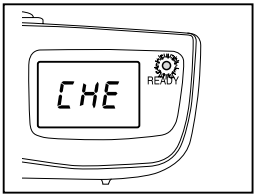


2 Release the RESET button immediately after "CHE" is displayed on the display window.

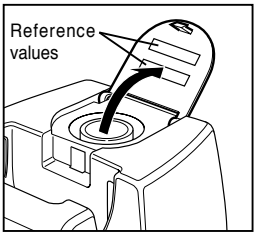


◆ If the RESET button is held down for more than 15 seconds, the unit of measurement will be switched. If this occurs, switch the unit back to the previous one. (For the method of switching the unit of measurement, refer to **"Selecting the Unit of Measurement"** on page 19.)

3 Check to confirm that "CHE" is displayed and that the READY lamp is illuminated.

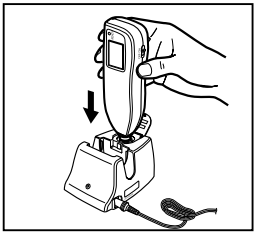


4 Open the checker cover.



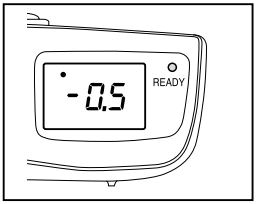
5 Place the measuring probe perpendicular to the checker, and push it gently until a click is heard.

◆ If the measuring probe is contacted aslant with the checker, place it perpendicularly and take measurement again.



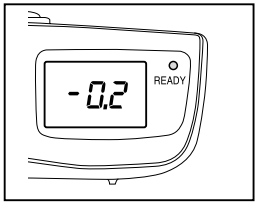
6 Confirm the measured value.

◆ The display will interchange between the L value (measured value of the long optical path) and the S value (measured value of the short optical path). **"●"** appears in the upper left corner of the display while the L value is displayed.



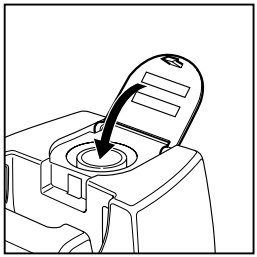
L value (measured value of the long optical path)

◆ The values are acceptable if both the L value and S value are within ±1.0 of the reference values indicated on the checker cover. (The L and S values indicate the hardware characteristics.)
If the measured value exceeds ±1.0 of the reference value, clean both the checker and probe, then take measurement again.
If ±1.0 of the reference value is still exceeded, contact the nearest KONICA MINOLTA SENSING authorized service facility.

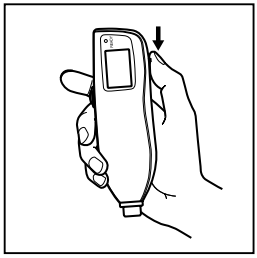


S value (measured value of the short optical path)

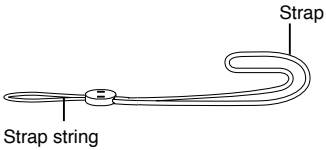
7 Close the check cover.



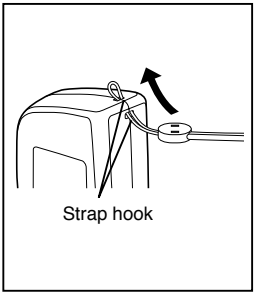
8 Set the POWER switch to OFF.



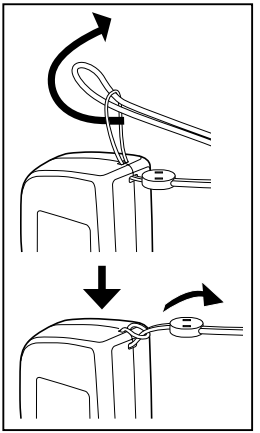
3) Attaching the Strap



1 **Pass the strap string through the strap hook.**



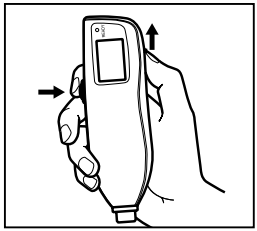
2 **Pass the strap through the loop of the string and then pull it to secure as shown.**



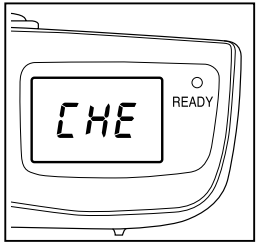
4) Selecting the Unit of Measurement

● The unit of measurement can be switched by pressing the POWER switch and RESET button together.

1 **Set the POWER switch to ON while holding down the RESET button.**



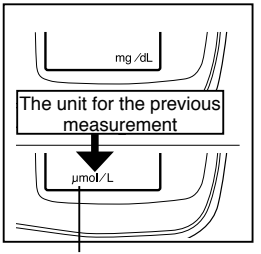
2 **"CHE" will appear on the display, but leave the RESET button held down.**



- ◆ The unit of measurement will be switched when approximately 15 seconds have elapsed.
- ◆ If the RESET button is released while **"CHE"** is displayed on the display, the check mode will be activated.

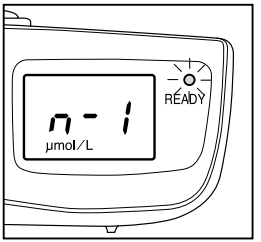
3 Check that the unit of measurement has been switched.

◆ **"CHE"** will disappear and the unit of measurement is displayed.



When switching the unit of measurement, the one for the previous measurement will not be displayed. The newly selected unit of measurement is displayed. (An example of switching from "mg/dL" to "µmol/L" is shown above.)

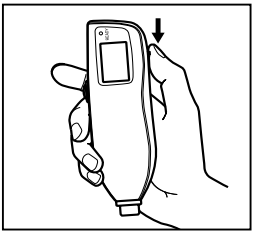
4 Release the RESET button.



◆ The READY lamp will light up, indicating that the instrument is ready for measurement.

◆ Switching of the unit of measurement is performed only once.
The unit of measurement will not be switched even if the RESET button is kept pressed.
To switch the unit of measurement again, set the POWER switch to OFF, and then repeat the above steps from **step 1**.

5 Set the POWER switch to OFF.

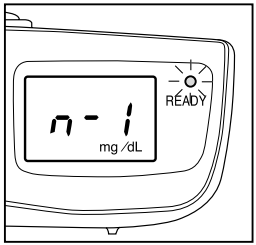


Measurement

This instrument allows **"single measurement"**, that handles the result taken from each measurement as the measured value, and "average measurement" that handles the average of the results taken from two to five measurements as the measured value. The number of measurements to be taken must be set according to the measuring point and measurement state.

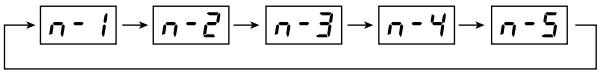
Setting the Number of Average Measurements

1 **Set the POWER switch to ON or press the RESET button to ready the instrument for measurement.**

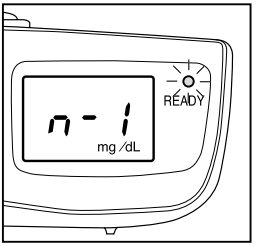


- **"n-1"** to **"n-5"** are displayed according to the settings made for the previous measurement.

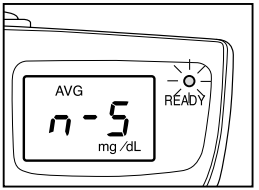
2 **Hold down the RESET button for five seconds. The number of average measurements will switch as follows.**



3 Release the RESET button while the desired number of average times is displayed. This will record the displayed number of average times.



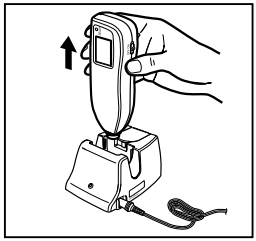
- **n-1: Single measurement**
  Displays the result taken from a single measurement as the measured value.
- **n-2 to n-5: Average measurement**
  Displays the average of the results taken from two to five measurements as the measured value.
  If **"2"** to **"5"** is selected, **"AVG"** will appear in the upper left corner of the display.



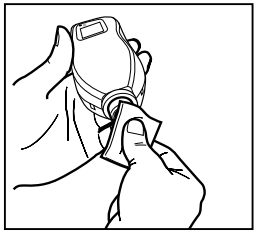
Measuring Procedure

Removing from Charger

1 **Remove the main body from the charger.**

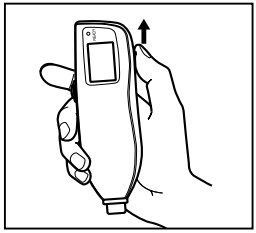


2 **Clean the measuring probe with medicinal alcohol.**



3 **Set the POWER switch to ON.**

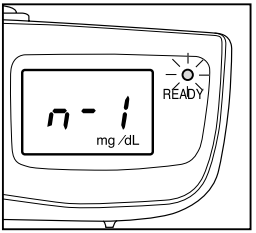
- The READY lamp will light up after a few seconds, indicating that the instrument is ready for measurement.
- If the instrument is not operated for more than 60 seconds, the back-light on the display and READY lamp will go out. In this case, press the RESET button to ready the instrument for measurement.



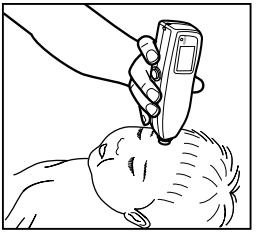
Single Measurement

Make sure that single measurement is selected.
(For the method of setting the number of measurements to be taken, refer to **"Setting the Number of Average Measurements"** on page 21.)

4 **While "n-1" is displayed, make sure that the READY lamp is lit.**

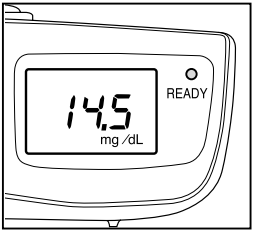


5 **Place the measuring probe against the point to be measured, and push it gently until a click is heard.**



- The instrument's xenon lamp will flash momentarily, and the measured value will appear on the display.
- If the instrument is not operated for more than 60 seconds, the back-light on the display will go out.

6 **Reading the value.**



- If the measured value blinks, the value is outside the guaranteed measurement accuracy range. If **"-0-"** is displayed, the measured value is outside the display range.
  (For details of the guaranteed mea-

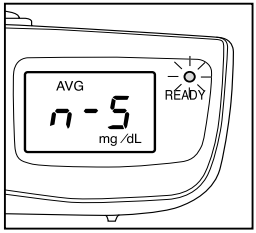
surement accuracy range or the display range, refer to the column of page 27 on this manual.)

- To exit measurement, proceed to **step 7.** To take another measurement, press the RESET button and continue from **step 4**.

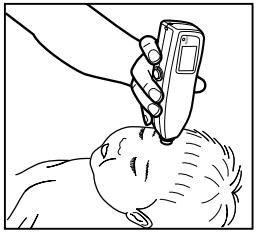
Average Measurement (example using five times as the average)

Make sure that average measurement is selected.
(For the method of setting the number of measurements to be taken, refer to **"Setting the Number of Average Measurements"** on page 21.)

4 **Check to ensure that the READY lamp is illuminated once "n-5" has been displayed.**

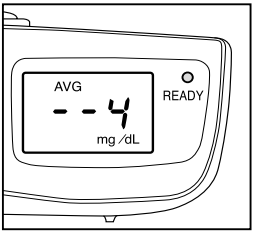


5 **-1 Place the measuring probe vertically on the area to be measured, and then apply gentle pressure until it clicks into place.**



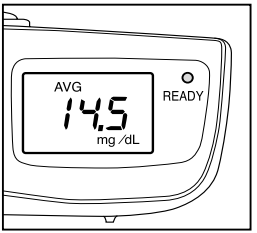
- The measurement will be carried out and the number of remaining measurements will be displayed.

5 -2 While making sure that the READY lamp is lit, repeat the remaining number of measurements.



- When the remaining number of measurements is completed, the average of the measured values will be displayed.
- If the instrument is left without performing the remaining measurements, no measured value will be displayed, the instrument will no longer be ready for measurement, and the average measurement will be cancelled. To perform average measurement again, press the RESET button and repeat the above steps from **step 4**.

6 Reading the value.



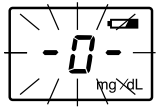
- If the measured value blinks, the value is outside the guaranteed measurement accuracy range. If **"-0-"** is displayed, the measured value is outside the display range.
  (For details of the guaranteed measurement accuracy range or the display range, refer to the column of page 27 on this manual.)
- To exit measurement, proceed to **step 7**. To take another measurement, press the RESET button and continue from **step 4**.

Regarding the measurement accuracy

- If the measured value is outside the measurement range (25.1 to 30.0 mg/dL, 426 to 510 μ mol/L), it will blink.
  This means that the value is outside the guaranteed measurement accuracy range.

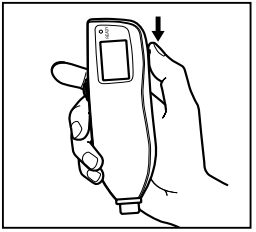
Regarding outside the display range

- If the measured value is outside the display range (i.e. exceeds 30.1 mg/dL, 511 μ mol/L), "**-0-**" will be displayed.

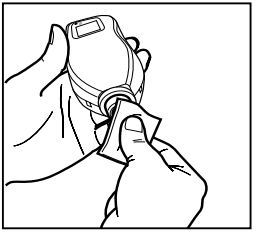


Storing the Instrument

7 **Set the POWER switch to OFF.**

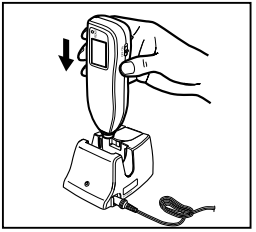


8 **Clean the measuring probe with medicinal alcohol.**



9 **Place the instrument on the Charger unit.**

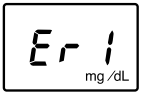
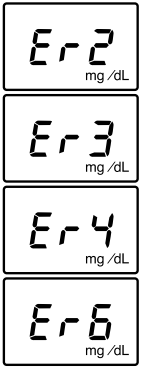
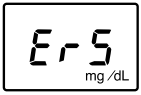
◆ When the instrument is not in use, keep it placed on the Charger unit.



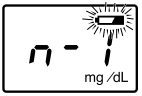
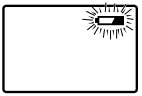
Trouble Shootings

Error Messages

The following warnings may be displayed on the display window.

Error Message	Cause	Solution
	The measured value is abnormal. In the case of average measurement, measurement fluctuation is excessively large.	Place the measuring probe perpendicular to the recommended point (forehead or sternum) and take measurement again.
	It is possible that a measurement error has occurred during average measurements, or a malfunction has arisen in the hardware.	Set the POWER switch to OFF, wait 10 seconds or more, and then set it to ON again. If this warning still reappears, contact the nearest KONICA MINOLTA SENSING authorized service facility.
	There is a possibility that charging is insufficient.	Set the POWER switch to OFF, and then place the instrument on the charger unit to charge it. If this warning still reappears, contact the nearest KONICA MINOLTA SENSING authorized service facility.

Battery Indication

Indicate	Cause	Solution
 Battery mark is blinking.	Battery power is getting low.	Although approximately 50 measurements can still be taken continuously after this warning appears, it is recommended that the battery be charged as soon as possible.
 Only the battery mark is displayed.	Battery has run out.	Set the instrument to the charger, and charge the battery.
None are displayed.	Battery is completely exhausted.	Set the instrument to the charger, and charge the battery.

Check Points before Repairing

If an abnormality occurs with the instrument, check and take necessary action as given in the table below. If the abnormality still reappears, set the POWER switch to OFF, wait 10 seconds or more, and then set it to ON again.

If the abnormality continues to reappear, contact the nearest KONICA MINOLTA SENSING authorized service facility.

Problem	Check point	Solution	Ref. Page
The display is blank even if the POWER switch is set to ON. The display suddenly goes blank during measurement.	Are the batteries exhausted?	Place the instrument on the charger unit to charge it.	13
	Have the batteries been left 60 seconds or more after setting the SET switch to ON?	Press the RESET button to ready the instrument for measurement.	23
The charger lamp does not light up even if the instrument is placed on the Charger unit.	Are the Charger unit and AC adapter connected to an AC outlet correctly?	Connect the Charger unit and AC adapter correctly.	14
	Is the instrument placed perpendicular to the measuring point?	Place the main body correctly.	
Not possible to take measurements.	Is the READY lamp lit?	First check that the READY lamp is lit, and start measurement.	21
		If the remaining battery voltage is low or if the battery is exhausted, place the instrument on the charger unit to charge it.	13

Maintenance and Inspections

- Before using the instrument, make sure that there is no dam-age to the instrument, no damage or wire-breakage in the power cord and the instrument operates correctly and safely.
  (For the method of checking operation of the instrument, refer to **"Inspecting"** on page 15.)

Cleaning

- Dampen a soft cloth with neutral detergent or water, wipe the instrument with it, then wipe off carefully with a dry cloth. In this way, make sure the instrument is cleaned and never use solvent.
  When cleaning, take care not to touch the connector terminals. Touching them may break terminal pins, resulting in breakdown or damage.
- When cleaning the measuring probe, wipe it with a cloth dampened with disinfectant alcohol.

Specifications

■ Model name	Jaundice Meter JM-103
■ Measuring method	Determines yellowness of subcutaneous tissue by using two optical paths to measure optical density difference at two wavelengths
■ Measurement range	0.0 to 25.0 mg/dL or 0 to 425 μ mol/L
■ Accuracy (σ)	±1.5 mg/dL or ±25.5 μ mol/L
■ Light source	Pulse xenon arc lamp
■ Light source life	150,000 measurements
■ Sensors	Silicon photodiodes

■ Operating conditions

Temperature/humidity range:

0 to 40°C (32 to 104°F); 30 to 85% relative humidity with no condensation

Atmospheric pressure/altitude range:

700 to 1060hPa (altitude: -400 to 3000m)

■ Storage conditions

Temperature/humidity range:

-10 to 60°C (14 to 140°F); 10 to 95% relative humidity with no condensation

Atmospheric pressure/altitude range:

700 to 1060hPa (altitude: -400 to 3000m)

■ Power

JM-103 main body:

Built-in Ni-MH battery (Approximately 400 measurements when fully charged)

AC Adapter:

Rated input: 100 to 240V, 50/60Hz, 9-13VA

Rated output: 9V 500mA, 4.5W

■ Dimensions 48 mm(W) x 154 mm(H) x 32 mm(D)

■ Weight 150 g (with Ni-MH battery)

■ Other Averaging function

■ Standard accessories

Charger unit (with a built-in reading checker) JM-A30, Strap, Soft Case JM-A61, AC adapter JM-A31

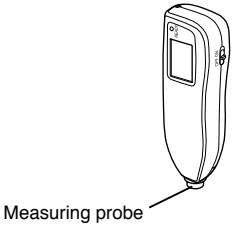
■ Usable life

5 years [Verified by KONICA MINOLTA SENSING, INC. (based on own data)]

■ Components that touch the body

Measuring probe:

Polyacetal, stainless pipe, optical fiber (multi-component glass)



❍ Equipment classification (based on “UL 60601-1/EN 60601-1”)
- Protection against electric shock: Internally powered
- Type of applied part: BF
- The instrument is not protected against entry of water.
- Only the cleaning method has been stipulated (no disinfection/sterilization methods have been stipulated).
- Mode of operation of Equipment: Continuous while in Use (IEC 60601-1)

Appendix

EMC Guidance (electromagnetic emissions)

Guidance and manufacture's declaration - electromagnetic emissions		
The Model JM-103 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model JM-103 should assure that it is used in such an environment.		
Emissions test	Compliance	Electriomagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Model JM-103 uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electromagnetic equipment.
RF emissions CISPR 11	Class B	The Model JM-103 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

EMC Guidance (electromagnetic immunity)

Guidance and manufacture's declaration - electromagnetic immunity			
The Model JM-103 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model JM-103 should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electromagnetic Discharge (ESD) IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile, if fllors are covered with synthetic materisl, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short Interruptions and Voltage variations on power supply Input lines IEC61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40 % U_T (60% dip in U_T) for 5 cycle 70 % U_T (30% dip in U_T) for 25 cycle <5% % U_T (>95% dip in U_T) for 5 sec	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40 % U_T (60% dip in U_T) for 5 cycle 70 % U_T (30% dip in U_T) for 25 cycle <5% % U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the JM-103 requires continued operation during power mains interruotions, it is recommended that the JM-103 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at level characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration - electromagnetic immunity

The Model JM-103 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model JM-103 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the JM-103, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance inmeters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the JM-103 is used exceeds the applicable RF compliance level above, the JM-103 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the JM-103.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Measuring Principle

The Jaundice Meter JM-103 determines the yellowness of the subcutaneous tissue of a newborn infant by measuring the difference in optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions. The measuring probe has two optical paths (see Fig. 1). The use of this method allows measurement of yellowness of the skin and subcutaneous of a newborn infant with the influences of melanin pigment and skin maturity kept at a minimum, which was impossible with conventional methods.

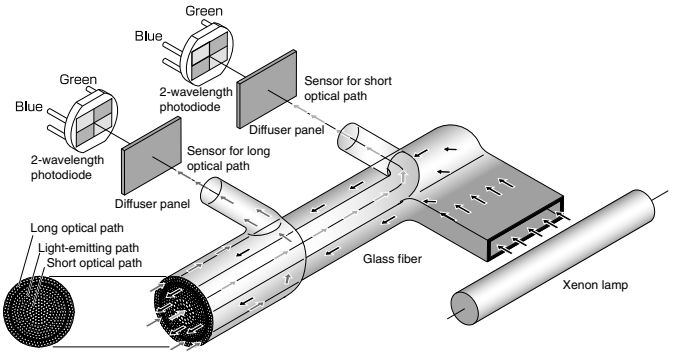


Fig. 1

When the measuring probe is pressed against the forehead or sternum of the infant, the built-in xenon lamp flashes, and the light from the xenon lamp is guided to the skin surface through the glass fiber and illuminates the skin. The light is then scattered and absorbed in the skin repeatedly, and finally returns to the glass fiber (sensor side). Of the light that returns to the fiber, the part scattered from shallow areas of the subcutaneous tissue passes through the inner core (short optical path) of the fiber while the part scattered from deep areas of the subcutaneous

tissue passes through the outer core (long optical path), and then they reach their corresponding photodiode.

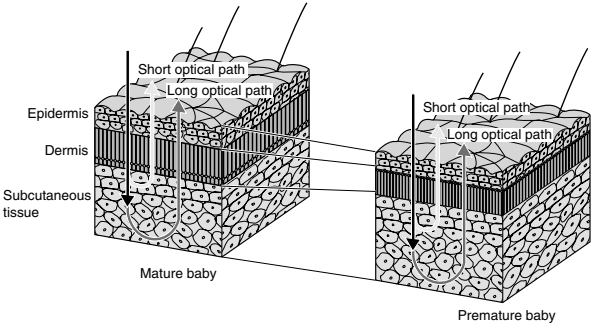


Fig. 2

By calculating the difference in optical densities, the parts that are common to the epidermis and dermis will be deducted, and as a result the difference in optical densities between the two wavelength regions can be obtained for the subcutaneous tissue only. Since the optical density difference shows a linear correlation with serum bilirubin concentration, it is converted to serum bilirubin concentration and indicated digitally.

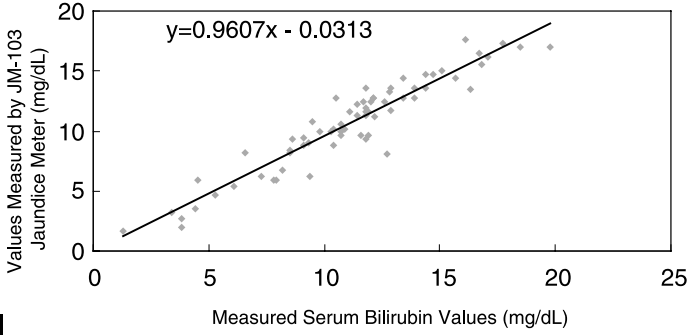
Clinical Test Result Report

To verify serviceability of the JM-103 Jaundice Meter, the correlation between values measured by the instrument and the serum bilirubin was measured at three domestic hospital facilities.

The standard deviation (σ) from the regression line obtained at that time was ±1.24.

✻: The standard deviation (σ) being ±1.24 means that approximately 68% of the data taken from measurements performed on a living body is within this range.

Correlation between Serum Bilirubin Values and those Taken by JM-103 Jaundice Meter



Data quantity n=69

KONICA MINOLTA

Manufacturer
KONICA MINOLTA SENSING, INC.
3-91, Daisen-nishimachi, Sakai-ku, Sakai-shi, Osaka 590-8551, Japan

©2002-2006 KONICA MINOLTA SENSING, INC.

9222-1712-12 AGGBKX(2) Printed in Japan